COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 05-V-2006
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NOT FOR PUBLICATION

COMMISSION DECISION

of 05-V-2006

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION DECISION

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amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the third subparagraph of Article 4(5), and the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Sanofi-Aventis Deutschland GmbH on 28 November 2005 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the notification submitted by Sanofi-Aventis Deutschland GmbH under Article 4(1) of Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 March 2006,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Apidra - Insulin glulisine", which is entered in the Community Register of Medicinal Products under No(s)

[1] OJ L 136, 30.4.2004, p. 1
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

EU/1/04/285/013-020 and the placing on the market of which was authorised by Decision C(2004)3653 of 27 September 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)3653 accordingly.

(3) The European Medicines Agency acknowledged, between 16 September 2005 and 23 March 2006, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.

(4) Sanofi-Aventis Deutschland GmbH submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2004)3653 of 27 September 2004.

(5) The marketing authorisation should be updated, and Decision C(2004)3653 amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/557/IA/9	(EU/1/04/285/001-028)

2) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/557/N/6	IIIAB (EU/1/04/285/001-028)

3) Annex I is replaced by the text set out in Annex I to this Decision;

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

4) Annex II is replaced by the text set out in Annex II to this Decision;

5) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, D 65926 Frankfurt am Main, DEUTSCHLAND.

Done at Brussels, 05-V-2006

For the Commission
Heinz ZOUREK
Director-General